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# (54) Embolic coils with offset helical and twisted helical shapes

Emboliespirale mit abweichenden Achsen und gedrehten Formen

Spirale embolique avec des formes d'hélices désaxées et vrillées

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(56) References cited:
**WO-A-92/14408**
**US-A- 4 994 069**
**US-A- 5 122 136**
**US-A- 5 217 484**
**US-A- 5 304 194**



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## Description

This invention is a surgical device. In particular, it is a flexible device for forming a vasoocclusion or embolism. Typically, it is a helically wound coil in which the helix is wound in such a way as to have multiple, axially offset, longitudinal or focal axes. Another important facet of the invention is the presence of small diameter secondary coil windings adjacent large diameter coil windings. The device is sufficiently flexible and small that it may be delivered to a site within the vasculature of the human body using a pusher and a catheter. The device is generally linear when within the catheter but relaxes to form the multi-focal form after delivery from the distal end of the catheter lumen. Various mechanical connections may also be used to discharge the inventive coil from its pusher. Similarly, the coil may be attached to a pusher using a sacrificial joint, which sacrificial joint is dissolved by imposition of a small voltage within the human body. The device may be used alone or in conjunction with other coils or with a fibrous thrombotic attachments or the substrate to localize subsequent infusion of tissue adhesives, other particulate embolization devices, or chemotherapeutic agents in abnormal blood vessels and tissues.

Endovascular therapy has been used in treating a variety of different conditions, including control of internal bleeding, occlusion of blood supply to tumors, and relief of vessel wall pressure in the region of areurysm. A variety of different embolic agents are known as arguably suitable for such therapy.

One known embolic agent includes injectable fluids or suspensions, such as microfibrillar collagen, various polymeric beads, and polyvinyl alcohol foam. The polymeric agents may be additionally crosslinked, sometimes *in vivo*, to extend the persistence of the agent at the desired vascular site. These agents are often introduced into the vasculature through a catheter. After such introduction, materials there form a solid space-filling mass. Although they provide good short-term vasoocclusion, they are ultimately reabsorbed in the process of vessel recanalization.

Polymer resins, typically cyanoacrylates, are also employed as injectable vasoocclusive materials. The resins are typically mixed with a radio-opaque contrast material or made radiopaque by the addition of tantalum powder. Their use is fraught with problems in that precise placement of the mixture is quite difficult. The creation of inadvertent embolisms in normal vasculature due to the inability of controlling the destination of the pregelled resins is not altogether uncommon. The material is also difficult or impossible to retrieve once it has been placed in the vasculature. Such resins have not been FDA approved, and a waiver must be requested in each instance where the materials are applied during human operative procedures. A number of mechanical vasoocclusive devices are widely used. One such device is a balloon which may be carried to the vessel site at the end of the catheter and there inflated with a suitable fluid, typically a polymerizable resin, and released from the end of the catheter. The balloon device has the advantage that it effectively fills the cross-section of the occluded vessel. However, when using intravascular balloon embolization of intracranial berry aneurysms, inflation of a balloon into the aneurysm carries some risk of aneurysm rupture due to possible "overfilling" of portions of the sac and due to the traction produced when detaching the balloon from the end of the catheter. Moreover, a vascular balloon is difficult to retrieve after the resin within the balloon sets up, and the balloon cannot be easily visualized using radiographic techniques unless it is filled with contrast material. Balloons have also been known to rupture during filling, or release prematurely during filling, or leak monomeric resin into the vasculature during the period before the monomer sets up into polymeric form.

Another type of mechanical vasoocclusive device is a wire coil or braid which can be introduced through a catheter in stretched linear form and assumes an irregular shape upon discharge of the device from the end of the catheter. A variety of vasoocclusive coils and braids are known. For instance, US-A-4,994,069, to Ritchart et al., shows a flexible, preferably coiled, wire for use in small vessel vasoocclusion. Unlike vasoocclusive coils shown previously, Ritchart et al. teaches a coil which is fairly soft and is delivered to the site using a pusher within a catheter lumen. The Ritchart et al. coils are typically pushed into the desired vascular site in a linear configuration. Upon discharge from the catheter, the coil may undertake any of a number of random or regular configurations designed to fill the site. The coils are used for small vessel sites, e.g., 0.5-6 mm in diameter. The coils themselves are said to be between 0.25 and 0.76 mm (0.010 and 0.030 inches) in diameter. The length of the coiled wire is typically 15-20 times the diameter of the vessel to be occluded. The wire used to make up the coils may be 0.05 to 0.15 mm (0.002 to 0.006 inches) in diameter. Tungsten, platinum, and gold threads or wires are said to be preferred. These coils have a variety of benefits, including the fact that they are relatively permanent, they can be easily imaged radiographically, they may be located at a well-defined vessel site, and they can be retrieved.

A variation of the mechanical endovascular coil is the electrolytically detached endovascular coil described in US-A-5,122,136, to Guglielmi et al. Guglielmi's coils are typically used in intracranial aneurysms because of their effectiveness in quickly forming controlled emboli. The disclosed coils are similar to those of Ritchart et al. in size and in composition. However, the method of introducing the coil to the vascular site is somewhat different. Rather than mechanically thrusting the coil into the chosen site, the coil is placed at the site and a small voltage is applied to the guidewire supporting the coal so that the coil is electrolytically detached from the distal tip of the guidewire.

The step of electrolytically detaching the coil has the added benefit of forming a thrombus as the coil is detached. Again, as noted above, the Guglielmi coils may be stainless steel or platinum or the like, and are typically 0.25 to 0.51 mm (0.010 to 0.020 inches) in diameter and are made using wire having approximate diameters of 0.025 to 0.13 mm (0.001 to 0.005 inches). The coils in this service are typically between 1 and 50 centimeters in length.

A variation of vasoocclusive coils having both secondary structures and external thrombogenic fibrous coverings may be found in US-A-5,382,259 to Phelps et al. This patent shows a helical coil having a number of secondary shapes such as those seen in the Ritchart et al. patent discussed above. However, larger sized devices and braided coverings of various configurations are disclosed therein as well.

None of the abovementioned references suggest or show a vasoocclusive device having multiple longitudinal axes.

WO-A-92/14408 discloses a plurality of different designs of vaso-occlusive device. In one embodiment in particular (the Figure 4 embodiment) a helically wound coil has two primary coil ends and a primary diameter. This helically wound coil is further wound into a secondary coil configuration having first and second secondary coil ends. This secondary coil configuration comprises two longitudinal focal axes extending generally parallel to each other and between the first and second secondary coil ends. Of the loops of the coil, alternate ones of the loops extend circumferentially around different longitudinal focal axes.

According to the present invention there is provided a flexible, vaso-occlusive device for placement in a vascular lumen, comprising a helically wound coil having two primary coil ends and a primary diameter, said helically wound coil being further wound into a relaxed secondary coil configuration made up of at least two repeating units of loops and having first and second secondary coil ends and wherein the relaxed secondary coil configuration comprises more than two longitudinal focal axes extending generally parallel to each other and between said first and second secondary coil ends and wherein loops from both of said at least two repeating units extend circumferentially and independently about each of said more than two longitudinal focal axes forming said relaxed secondary coil configuration.

The embodiments of vasoocclusive device hereinafter described and illustrated comprise a helical coil which is wound in such a way that, in addition to its primary helical structure, it has a secondary helical structure with at least two focal axes, in many cases at least three focal axes. Another facet of some of the embodiments is the presence of small diameter secondary coil windings adjacent large diameter coil windings. The resulting devices are sufficiently soft (but retain sufficient memory) that they may be introduced through a catheter in a linear condition and, when released from the distal end of the catheter, relax to form this multifocal form. The resulting relaxed forms are ones which occupy a significant cross-sectional area when compared to the cross-sectional area of the catheter lumen through which the devices are delivered. It is the use of multiple axes which results in such a loose structure after deployment.

Each device may be used in conjunction with fibrous covering or attachments to increase the propensity of the device for forming thrombus. It may additionally be used in conjunction with other coils, braids, or chains to achieve denser occlusions or as a substrate to localize a subsequent infusion of tissue adhesives, particulate embolization devices, or chemotherapeutic agents in abnormal blood vessels and tissues. The device may have ends which are mechanically detachable from the pusher used to eject the coil or it may have an end which is electrolytically severable via the imposition of a small voltage to the pusher. It may also be used for the temporary occlusion of blood vessels during types of diminished blood flow testing. The device may be coated with thrombotic or therapeutic materials.

Figures 1 and 2 show schematic side and end views, respectively, of a typical vasoocclusive coil made according to this invention so to provide the conventions for discussing this invention.

Figures 3, 4 ,5, 7, 8, 9, and 10 show end views of various multi-focal coils made according to this invention.

Figure 6 shows an end view of a coil not in accordance with the present invention.

Figure 11 shows a highly desirable electrolytically severable joint for use with the coils of the invention.

Figure 12 shows a mechanically detachable joint for use with the coils of the invention.

Figures 13A, 13B and 13C show a method for winding a typical multi-focal coil according to this invention.

Figures 14A, 14B and 14C show a method for deploying the coils of this invention using a catheter.

This invention deals with vasoocclusive coils which are wound in such a way as to have multiple axes or focal lines. The devices are fairly straightforward in that they are typically formed by wrapping or winding a fine filament or wire typically having a diameter between about 0.06 and 0.13 mm (0.0025 inches and 0.005 inches), most preferably about 0.05 to 0.1 mm (0.002 to 0.004 inches). The vasoocclusive coils may be made out of a variety of materials. Some portion of the coils should be radiopaque so that its position may be readily monitored within the human body. Suitable materials include biocompatible metals, polymers, and alloys. For instance, biocompatible, radiopaque metals include platinum, palladium, rhodium, gold, silver, tungsten, iridium, and various stainless steels. Alloys such as platinum and tungsten (preferably 92-94% platinum and the remaining tungsten) are suitable and, indeed, are quite preferred. Most desirable platinum-tungsten alloys desirably have a tensile strength of at least about 1.24

MPa (180 kpsi) and, for a wire of a nominal 0.025 mm (0.001 inches) diameter, have a breaking load of 0.76 N (0.17 lbs.) with a minimum elongation of 2% measured at a speed of 0.42 mm/s (1.0 inches/minute). Various biocompatible polymers including polyethylene, polyurethane, polypropylene, and the like are suitable for use in these devices, but because of their lack of radiopacity, usually must be teamed with a radiopaque marker or filled with a radiopaque filler to allow proper positioning of the coil within the body. Similarly, other inorganic materials such as fibrous carbon are suitable and may be used in the invention.

It is also contemplated that the coils described herein be manufactured and used in conjunction with thrombotic materials such as various fibrous attachments, e.g., DACRON (Trade Mark), attached to the interior, exterior, or braided to the vasoocclusive coil in some fashion.

Figures 1 and 2 show a typical coil made according to the invention specifically for the purpose of describing the conventions used in describing the coils of this invention.

Figure 1 shows a vasoocclusive coil (100) having three "focal axes" (102) . These focal axes are generally parallel to the vascular lumen into which they are eventually placed. Although the vasoocclusive coil (100) shown in Figure 1 is in a so called "relaxed" condition--that is to say that it has been allowed to unwind from its linear condition in an unconfined space so to illustrate the shape of that unconfined coil--it should be understood that these focal axes may not bear a true relationship to the interior lumen of an artery or vein in that once they are confined, there may be some twisting or compression of the shape which will distort the unconfined shape into something quite different. Nevertheless, for purposes of description, the concept of focal axes (102) is instructive for describing the device. A focal axis is simply an axis about which a small helical coil has been wrapped. The focus (104) of this axis may be seen from an end view in Figure 2 of the device. Central to this invention is the presence of more than two of these focal axes (102). It is the presence of these at-rest focal axes which creates a three-dimensional space in the vasoocclusive coil which results in a large area or region of open but occluding structure in a vascular lumen. Another concept which is instructive in understanding this invention is that of a repeating unit (106) found in Figure 1. A repeating unit is simply the space in a vasoocclusive coil such as (100) in which the wound coil returns to a similar point on a specific focal axis. Finally, as shown in Figure 2, there are two other concepts which are of interest in describing this inventive device. They are the major effective diameter (108) and the minor effective diameter (110). The major effective diameter (108) is simply the widest relaxed dimension generally perpendicular to the focal axis (102) measured in a relaxed condition. The minor effective diameter (110) is the smallest diameter measured perpendicular to a focal axis (102) measured when the vasoocclusive coil is in a relaxed condition.

Again, the central concept of this invention is the creation of multiple focal axes in a vasoocclusive coil so to produce a vasoocclusive coil which may be introduced in a linear manner through a catheter and once that coil is ejected from the catheter, resulting in a coil having a high, typically regular, three-dimensional component once so ejected.

Figure 3 shows a variation of the inventive coil (112) similar to that shown in Figure 2 having three focal points. Figure 3 is an end view of the device and is one of the more simple of the inventive vasoocclusive coils made according to this invention. The relaxed shape seen in Figure 3 typically would not be present in the depicted form within the vascular lumen. More likely, the three foci (104) would be in more of a triangular shape, allowing some modest amount of pressure against the vascular lumen wall.

Figure 4 shows how vasoocclusive coil (112) might be situated in the lumen of an artery (114). The straight portions of coil (112) ((116) in Figure 3) are slightly deformed in Figure 4 to result in the pressure against the vascular lumen wall. The device (112) shown in Figures 3 and 4 clearly would have multiple repeating units (such as (106) in Figure 1) which may not be seen because of the perspective of Figures 3 and 4. Because of the shape and the short length of a typical repeating unit for such a device, it would be expected that the device have a sufficient number of repeating units to at least equal the major diameter of the device (as (108) in Figure 2). That is to say that the length of any of the focal axes in a Figure 3 and 4 device would be generally as long as the major diameter of the device. Although this is not a requirement of the invention, from a practical viewpoint, it may be necessary to ensure that the vasoocclusive coil stay in a position within a lumen.

Figure 5 shows another variation of the inventive vasoocclusive coil (118) in which there are four foci (104). Other than this difference in the number of foci (104), the device is similar in construction to that of the coil found in Figures 3 and 4. The loops about the foci (104) are small and produce long straight sections (116) between those loops.

Figure 6 shows a vasoocclusive coil that is not in accordance with the present invention. In this instance, the coil (120) is made up of a repeating unit having a large loop (122) and a smaller loop (124). The device has two foci (104). This coil as well as those shown in relation to the discussions to the figures above, results in a structure having a large cage-like structure which, depending upon the usage to which the vasoocclusive coils are placed, may be used either as a "framework" for placement of other coils such as those described in U.S. Patent Application Serial No. 0/978,320, filed November 18, 1992 entitled "ULTRASOFT EMBOLISM PRODUCING COILS AND PROCESS FOR USING THEM". It should be apparent that the smaller of the

diameter of the coil turns about the various focal axes and the shorter the distance between those focal axes, e.g., as shown by the distance (116) as shown in Figures 3 and .5, the more densely packed will be the resulting vasoocclusive coil once it is deployed into the vascular space.

Figure 7 shows yet another three foci (104) variation of the inventive vasoocclusive coil (126). The central turn (128) in this variation is small and the outerlying turns (130) are both somewhat larger. As may be conceptualized from Figure 8, this variation (126) produces a form within a blood vessel (114) which can provide additional force against the inner wall of that vessel (114) . This is so in that two extended portions (128) of larger loop (130) exert a force against the inner lumen when placed as shown in Figure 8. For vasoocclusive coil (126) wound in a similar material and spacing as compared to the coil shown in Figures 3 and 4, the Figures 7 and 8 variation would provide an added measure of hydrodynamic stability.

Figures 9 and 10, respectively, show end views of vasoocclusive coils having four and five foci. The added number of smaller coil turns about these foci, in combination with the high number of foci (104), provide variations in which the coils as deployed are quite dense. Both the Figure 9 coil (134) having four foci (104) and the Figure 10 coil (136) having five foci (104) are fairly "soft" in their deployment in that they are an indeterminate structure. It is possible and sometimes desirable to weave the devices made according to this invention in such a way that they would be determinate structures and less likely to deform within a vessel lumen. The study of "determinancy" is well known in structural engineering and no further comment need be made about it here for a complete description.

Each of the devices shown in Figures 2 through 10 may have a significant number of repeating units, e.g., four to sixteen or more.

As noted elsewhere, each of these devices may be pushed into the selected body site using typical pushers as are disclosed in Ritchart et al. Alternatively, the coils may be pushed from the deployment catheter and released using joints between the coil and pusher which joints have positive releasing features. For instance, Figure 11 shows a highly desirable electrolytically detachable joint assembly suitable for use with the coils of the invention. The severable joint region (141) is typically the extension of the core wire/pusher (149) which delivers the coil assembly (143) to the selected site in the human body. The severable joint region (141) is completely insulated (as is the exterior of the pusher assembly (145) except for a small band (147) which is often stripped of electrical insulation after the assembly is coated. The severable joint (147) erodes in the presence of blood when a small voltage is applied to the core wire (149). The severable joint (147) erodes in preference to the coil (143) because of the difference in the electronegativity between the less noble material of the joint (147) -- often stainless steel -- and the more noble material of the coil - - often a platinum alloy.

Once the joint (147) is eroded away, the coil may then stay as a implant and the pusher portion (145) may be removed from the body.

Details of the electrolytically detachable coil (more commonly known as the Guglielmi Detachable Coil or "GDC") are described in detail in US-A-5,122,136, issued June 16, 1992, and in US-A-5,354,295, issued October 11, 1994, both to Guglielmi and Sepetka. Improvements on the GDC joint are found in US-A-5,423,829, to Pham et al and in U.S. Pat. Appl. Ser. No. 08/431,827, filed April 28, 1995 also to Pham et al.

Figure 12 shows a variation of the invention in which the connective joint is a mechanically detachable joint. The depicted joint has a clasp section (153) which remains with the core wire or pusher (155) when the sheath (157) is retracted proximally. The other clasp section (151) remains with the coil (159) when the coil (159) is left in the body. Other mechanically detachable joints suitable for use with the inventive device are described in:

- US-A-5,234,437, to Sepetka, (shows a method of unscrewing a helically wound coil from a pusher having interlocking surfaces).

- US-A-5,250,071 to Palermo, (shows an embolic coil assembly using interlocking clasps mounted both on the pusher and on the embolic coil)

- US-A-5,261,916, to Engelson, (shows a detachable pusher-vaso-occlusive coil assembly having an interlocking ball and keyway-type coupling)

- US-A-5,304,195, to Twyford et al. (shows a pusher-vaso-occlusive coil assembly having an affixed, proximally extending wire carrying a ball on its proximal end and a pusher having a similar end, which two ends are interlocked and disengage when expelled from the distal tip of the catheter)

- US-A-5,312,415, to Palermo (also shows a method for discharging numerous coils from a single pusher by use of a guidewire which has a section capable of interconnecting with the interior of the helically wound coil).

- US-A-5,350,397, to Palermo et al. (shows a pusher having a throat at its distal end and a-pusher through its axis. The pusher sheath will hold onto the end of an embolic coil and will then be released upon pushing the axially placed pusher wire against the member found on the proximal end of the vaso-occlusive coil).

Figures 13A, 13B and 13C show a procedure for making coils according to this invention. Figure 13B, in

particular shows a method of making the Figure 6 coil which coil is not in accordance with the present invention. Figure 13C shows the final step (after the Figure 13B step) of making the Figure 2 variation of the inventive vasoocclusive coil.

Again, this is a very straightforward method once the concepts are explained. Vasoocclusive coils having secondary structures, such as are discussed in Ritchart et al. above, may be made using the winding step shown in Figure 13A. That is to say that a coil (150) made, e.g., of a platinum/tungsten alloy having a primary helical structure, is wound onto a first mandrel (152). This mandrel should be reasonably heat-tolerant in that a modest amount of annealing will take place in the later production steps of the method described here. If a coil having merely this simple single focal axis shape as shown in Figure 11A is desired, the coil (150) may be wound reasonably tightly over the mandrel (152) and subjected to a short heat treatment step at 177-593°C (350-1100°F) for a short period of time to allow the coil to be set into the noted form. Once the heat treatment is completed and the desired secondary shape has been infused into the coil, the coil may be removed from the mandrel and placed in a suitable delivery device. Many such coils are delivered using cannula which may be sterilized with relative ease.

The procedure shown in Figure 13A may be used as the first step for producing coils having multiple focal axes. Figure 13B shows the manner in which coil (150) is threaded with a second mandrel (154). Should the device having the configuration shown in Figure 6 be desired, the coil having mandrels (152) and (154) inserted therein would be then transported to the annealing oven for further treatment as noted above.

Figure 13B also shows the path taken by the third mandrel (158) as depicted in Figure 13C. The addition of mandrel (158) to the configuration of coil (150) as shown in Figure 13C will produce a device as shown in Figure 1 and in Figure 2.

Other procedures for introducing mandrels and turns should be apparent in producing the devices shown in the remainder of the drawings as well as in other three or more focal axis coils in accordance with this invention.

Figures 14A, 14B, and 14C show a procedure for introducing a vasoocclusive coil of the type described herein into an artery or other vascular site. This procedure is similar in many ways to the procedure described in Ritchart et al., mentioned above. The procedure is simply that a delivery catheter (170) is introduced into a region, e.g., an artery (172), until a desired site is reached. As is the case with most delivery catheters, a radiopaque marker (174) is included so that proper assessment of the site may be had. The coil of this invention (176) is shown within the distal portion of catheter (170). A pusher (178) is shown proximal of coil (176). Once the desired site is attained, pusher (178) is advanced as shown in Figure 16B. The coil (176), which until being ejected from the distal tip of catheter (170) has been in a linear configuration, relaxes to form the multi-focal configuration shown in Figure 14B. Figure 14C shows the withdrawal of catheter (170) and pusher (178) with the inventive coil (176) stationary within the lumen of artery (172).

## Claims

1. A flexible, vaso-occlusive device for placement in a vascular lumen, comprising a helically wound coil (100, 112, 118, 126, 134, 136, 143, 176) having two primary coil ends and a primary diameter, said helically wound coil being further wound into a relaxed secondary coil configuration made up of at least two repeating units of loops and having first and second secondary coil ends and wherein the relaxed secondary coil configuration comprises more than two longitudinal focal axes (102,104) extending generally parallel to each other and between said first and second secondary coil ends and wherein loops (128, 130) from both of said at least two repeating units extend circumferentially and independently about each of said more than two longitudinal focal axes forming said relaxed secondary coil configuration.

2. The device of claim 1, wherein the secondary coil configuration comprises multiple loops (128, 130) of said helically wound coil (100, 126), which loops include at least one comparatively smaller loop (128) between said first and second secondary coil ends.

3. The flexible device of claim 2, wherein said multiple loops (128, 130) include a plurality of said comparatively smaller loops, each said comparatively smaller loop (128) being adjacent a comparatively larger loop (130).

4. The device of claim 1, wherein the secondary coil configuration comprises at least one loop having a relatively smaller diameter located adjacent said first secondary coil end and multiple loops having relatively larger diameters located adjacent said second secondary coil end.

5. The device of claim 4, wherein the at least one loop having a relatively smaller diameter located adjacent said first secondary coil end is additionally adjacent said multiple loops having relatively larger diameters located adjacent said second secondary coil end.

6. The device of any one of the preceding claims, comprising a member selected from the group consisting of silver, gold, palladium, platinum, tungsten, iridium, stainless steel and alloys thereof.

7. The device of any one of the preceding claims, comprising an alloy of platinum and tungsten.

8. The device of any one of the preceding claims, wherein the coil (100, 112, 118, 126, 134, 136, 143, 176) comprises a biocompatible polymer.

9. The device of any one of the preceding claims, further comprising filamentary material attached to the helically wound coil (100, 112, 118, 126, 134, 136, 143, 176).

10. The device of claim 9, wherein the filamentary material attached to the helically wound coil (100, 112, 118, 126, 134, 136, 143, 176) is polyethylene terephthalate.

11. The device of any one of the preceding claims, wherein one of the primary coil ends comprises an electrolytically severable joint (147).

12. The device of any one of the preceding claims, wherein one of the primary coil ends comprises a joint (141) that is mechanically attachable to a pusher (145, 178).

**Patentansprüche**

1. Biegsame, gefäßverschließende Vorrichtung zum Einbringen in ein Gefäßlumen, umfassend eine spiralförmig gewickelte Spirale (100, 112, 118, 126, 134, 143, 176) mit zwei primären Spiralenden und einem primären Durchmesser, wobei die spiralförmig gewickelte Spirale des weiteren zu einer entspannten sekundären Spiralkonfiguration gewickelt ist, die aus wenigstens zwei sich wiederholenden Einheiten von Schlingen besteht und ein erstes und ein zweites sekundäres Spiralende aufweist, und wobei die entspannte sekundäre Spiralkonfiguration mehr als zwei längsgerichtete Brennachsen (102, 104) umfaßt, die im allgemeinen parallel zueinander und zwischen dem ersten und dem zweiten sekundären Spiralende verlaufen, und wobei Schlingen (128, 130) von beiden der wenigstens zwei sich wiederholenden Einheiten am Umfang und unabhängig von einander um jede der mehr als Zwei längsgerichteten Brennachsen verlaufen, die die entspannte sekundäre Spiralkonfiguration bilden.

2. Vorrichtung nach Anspruch 1, bei der die sekundäre Spiralkonfiguration eine Vielzahl von Schlingen (128, 130) der spiralförmig gewickelten Spirale (100, 126) umfaßt, wobei die Schlingen wenigstens eine vergleichsweise kleinere Schlinge (128) zwischen dem ersten und dem zweiten Spiralende umfassen.

3. Biegsame Vorrichtung nach Anspruch 2, bei der die Vielzahl von Schlingen (128, 130) eine Vielzahl der vergleichsweise kleineren Schlingen umfassen, wobei jede vergleichsweise kleinere Schlinge (128) neben einer vergleichsweise größeren Schlinge (130) liegt.

4. Vorrichtung nach Anspruch 1, bei der die sekundäre Spiralkonfiguration wenigstens eine Schlinge mit einem relativ kleineren Durchmesser im Bereich des ersten sekundären Spiralendes und eine Vielzahl von Schlingen mit einem relativ größeren Durchmesser im Bereich des zweiten sekundären Spiralendes umfaßt.

5. Vorrichtung nach Anspruch 4, bei der die wenigstens eine Schlinge mit einem relativ kleineren Durchmesser im Bereich des ersten sekundären Spiralendes außerdem neben der Vielzahl von Schlingen mit einem relativ größeren Durchmesser im Bereich des zweiten sekundären Spiralendes liegt.

6. Vorrichtung nach einem der vorhergehenden Ansprüche, umfassend ein Element, das ausgewählt ist aus der Gruppe umfassend Silber, Gold, Palladium, Platin, Wolfram, Iridium, Edelstahl und Legierungen derselben.

7. Vorrichtung nach einem der vorhergehenden Ansprüche, umfassend eine Legierung von Platin und Wolfram.

8. Vorrichtung nach einem der vorhergehenden Ansprüche, bei der die Spirale (100, 112, 118, 126, 134, 136, 143, 176) aus einem biokompatiblen Polymer besteht.

9. Vorrichtung nach einem der vorhergehenden Ansprüche, des weiteren umfassend ein an der spiralförmig gewickelten Spirale (100, 112, 118, 126, 134, 136, 143, 176) angebrachtes Fadenmaterial.

10. Vorrichtung nach Anspruch 9, bei der das an der spiralförmig gewickelten Spirale (100, 112, 118, 126, 134, 136, 143, 176) angebrachte Fadenmaterial Polyethylenterephthalat ist.

11. Vorrichtung nach einem der vorhergehenden Ansprüche, bei der eines der primären Spiralenden ein elektrolytisch lösbares Verbindungsstück (147) umfaßt.

12. Vorrichtung nach einem der vorhergehenden Ansprüche, bei der eines der primären Spiralenden ein Verbindungselement (141) umfaßt, das mechanisch an einem Schieber (145, 178) befestigt werden kann.

## Revendications

1. Dispositif vaso-occlusif flexible destiné à être disposé dans une lumière vasculaire, comprenant un serpentin enroulé hélicoïdalement (100, 112, 118, 126, 134, 136, 143, 176) comportant deux extrémités de serpentin principal et ayant un diamètre principal, ledit serpentin enroulé hélicoïdalement étant de plus enroulé sous une configuration de serpentin secondaire relâché constituée d'au moins deux unités répétées de boucles et comportant des première et deuxième extrémités de serpentin secondaire, et dans lequel la configuration de serpentin secondaire relâché comprend plus de deux axes focaux longitudinaux (102, 104) s'étendant globalement parallèlement l'un à l'autre et entre lesdites première et deuxième extrémités de serpentin secondaire, et dans lequel les boucles (128, 130) de toutes lesdites unités répétées au nombre d'au moins deux s'étendent circonférentiellement et indépendamment autour de chacun desdits axes focaux longitudinaux en un nombre supérieur à deux qui forment ladite configuration de serpentin secondaire relâché.

2. Dispositif selon la revendication 1, dans lequel la configuration de serpentin secondaire comprend des bouches multiples (128, 130) dudit serpentin enroulé hélicoïdalement (100, 126), ces bouches comprenant au moins une boucle comparativement plus petite (128) entre lesdites première et deuxième extrémités de serpentin secondaire.

3. Dispositif flexible selon la revendication 2, dans lequel lesdites bouches multiples (128, 130) comportent une pluralité desdites bouches comparativement plus petites, chacune desdites bouches comparativement plus petites (128) étant adjacente à une bouche comparativement plus grande (130).

4. Dispositif selon la revendication 1, dans lequel la configuration de serpentin secondaire comprend au moins une boucle ayant un diamètre relativement plus petit disposée au voisinage de ladite première extrémité de serpentin secondaire, et des boucles multiples ayant des diamètres relativement plus grands disposées au voisinage de ladite deuxième extrémité de serpentin secondaire.

5. Dispositif selon la revendication 4, dans lequel la boucle au nombre d'au moins une ayant un diamètre relativement plus petit, disposée au voisinage de ladite première extrémité de serpentin secondaire, est de plus adjacente auxdites boucles multiples ayant des diamètres relativement plus grands disposées au voisinage de ladite deuxième extrémité de serpentin secondaire.

6. Dispositif selon l'une quelconque des revendications précédentes, comprenant un élément choisi parmi le groupe comprenant l'argent, l'or, le palladium, le platine, le tungstène, l'iridium, l'acier inoxydable et des alliages de ceux-ci.

7. Dispositif selon l'une quelconque des revendications précédentes, comprenant un alliage de platine et de tungstène.

8. Dispositif selon l'une quelconque des revendications précédentes, dans lequel le serpentin (100, 112, 118, 126, 134, 136, 143, 176) comprend un polymère bibcompatible.

9. Dispositif selon l'une quelconque des revendications précédentes, comprenant de plus un matériau filamenteux fixé au serpentin enroulé hélicoïdalement (100, 112, 118, 126, 134, 136, 143, 176).

10. Dispositif selon la revendication 9, dans lequel le matériau filamenteux fixé au serpentin enroulé hélicoïdalement (100, 112, 118, 126, 134, 136, 143, 176) est du poly(téréphtlalate d'éthylène).

11. Dispositif selon l'une quelconque des revendications précédentes, dans lequel l'une des extrémités de serpentin primaire comprend un joint séparable électrolytiquement (147).

12. Dispositif selon l'une quelconque des revendications précédentes, dans lequel l'une des extrémités de serpentin primaire comprend un joint (141) qui peut être fixé mécaniquement à un poussoir (145, 178).

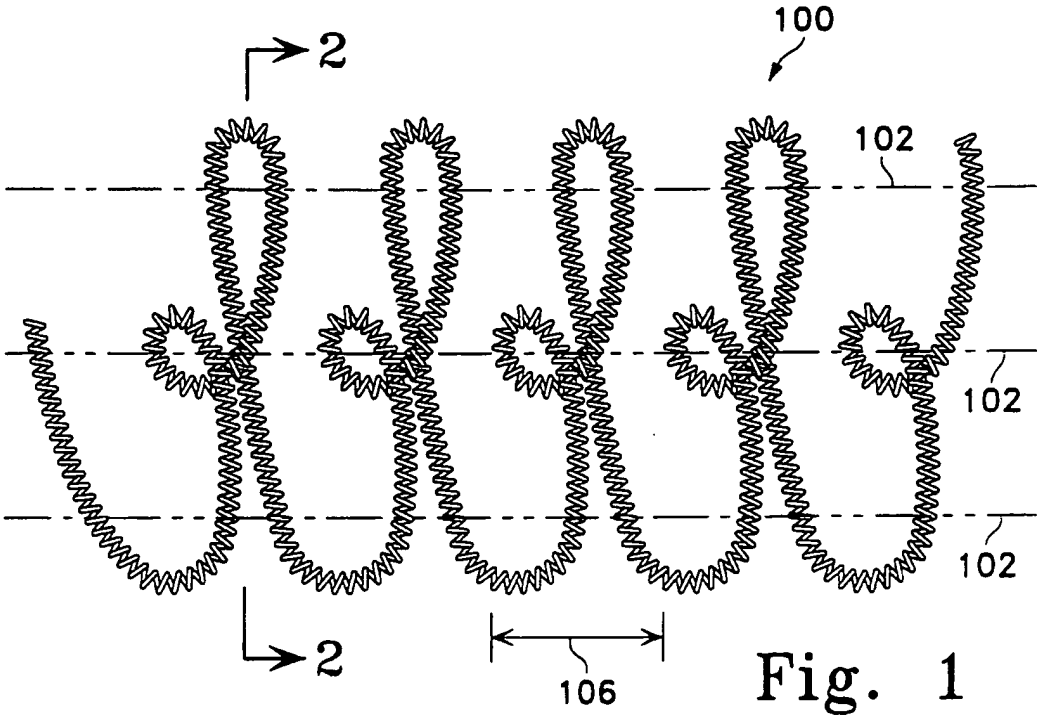



Fig. 1

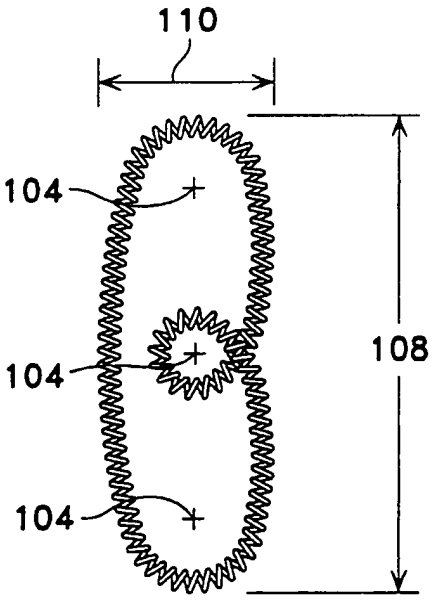



Fig. 2

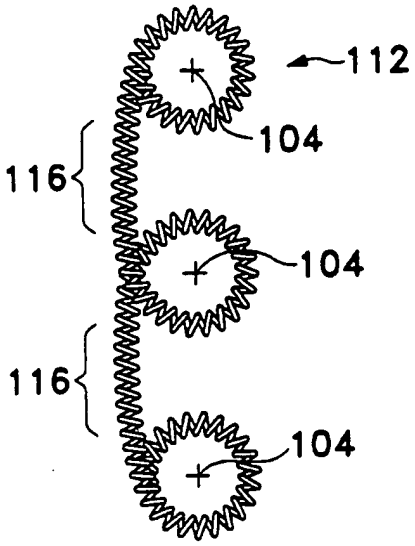



Fig. 3

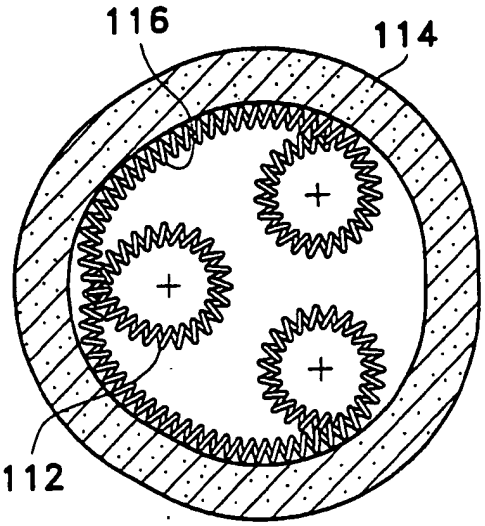



Fig. 4

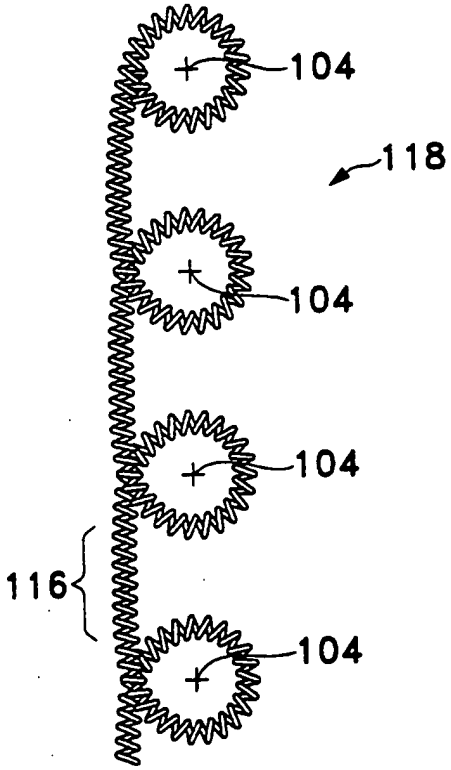



Fig. 5

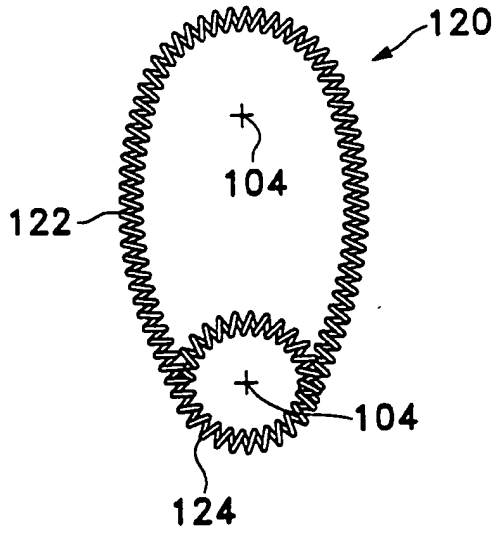



Fig. 6

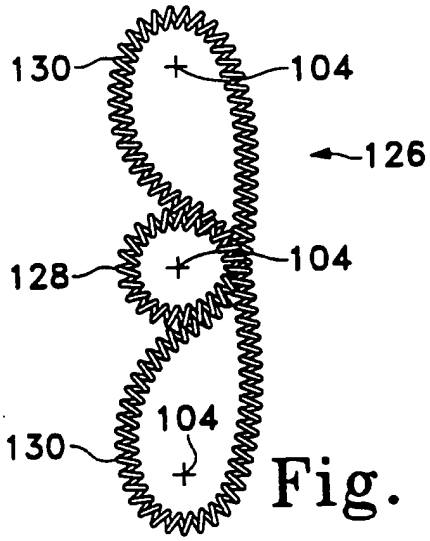



Fig. 7

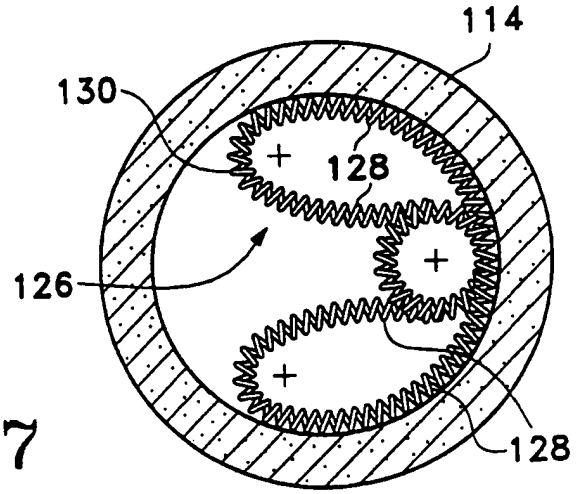



Fig. 8

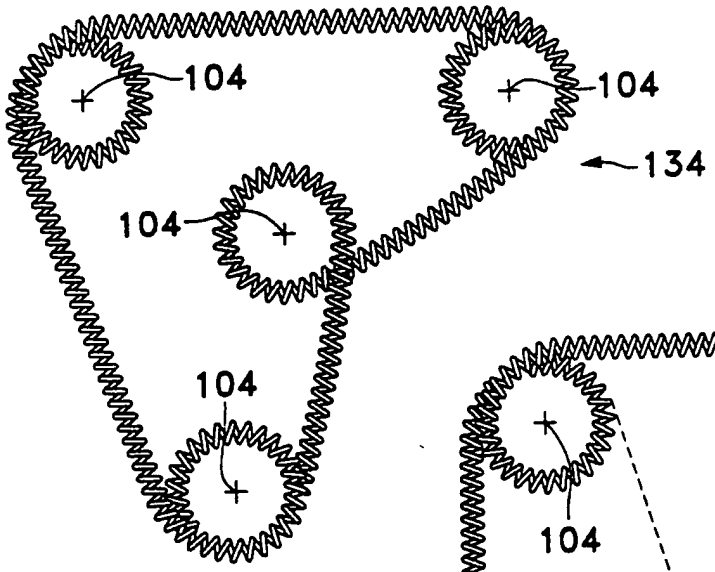



Fig. 9

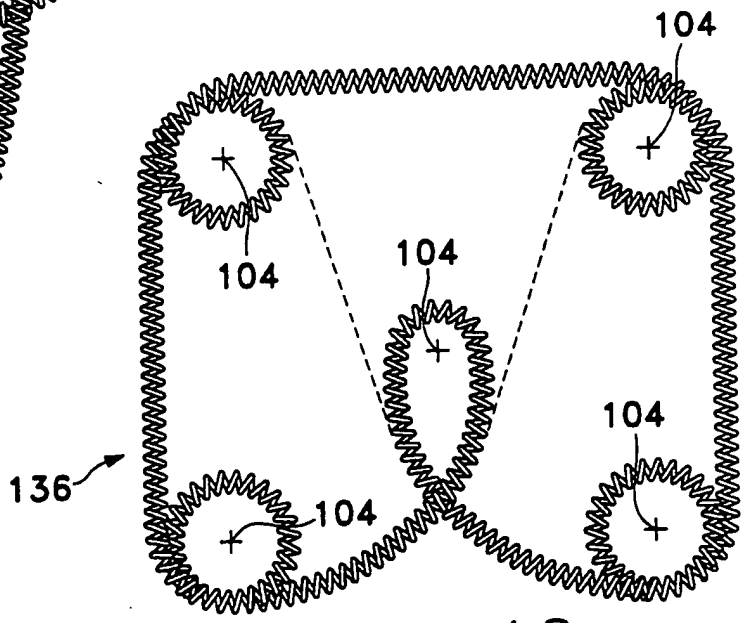



Fig. 10

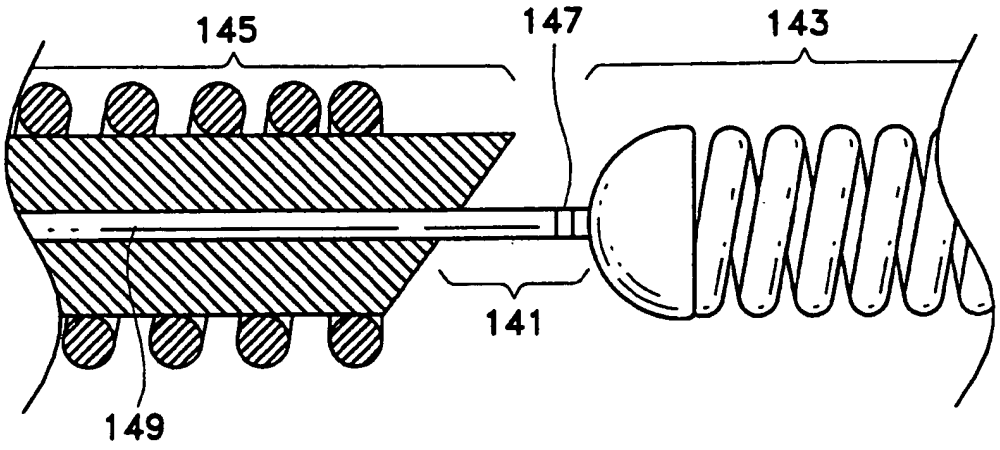



Fig. 11

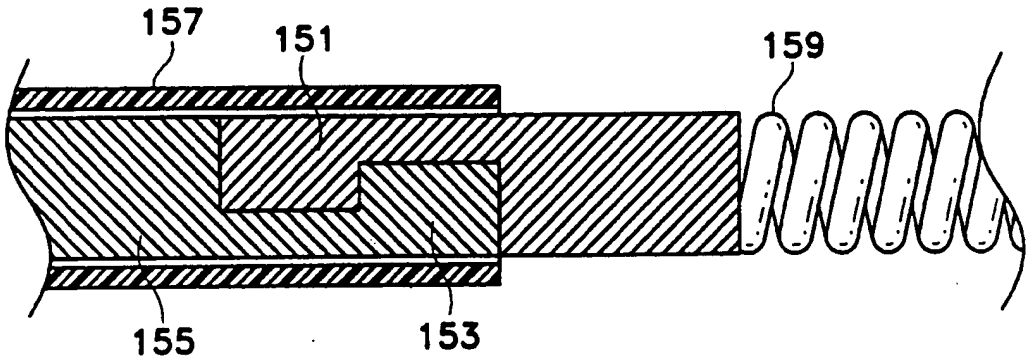
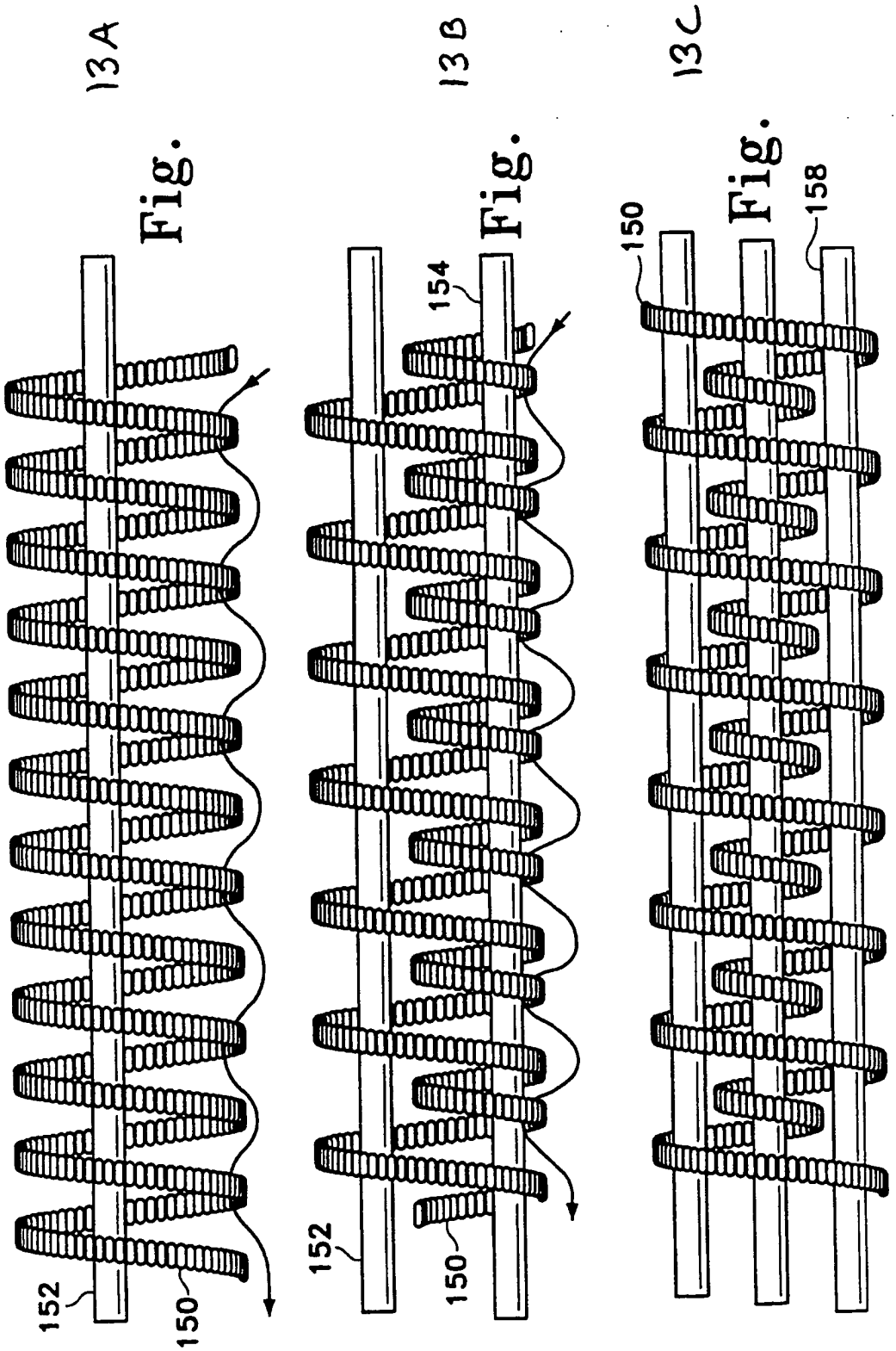



Fig. 12


13A
Fig.
152
150
13B
Fig.
154
152
150
13C
Fig.
150
158

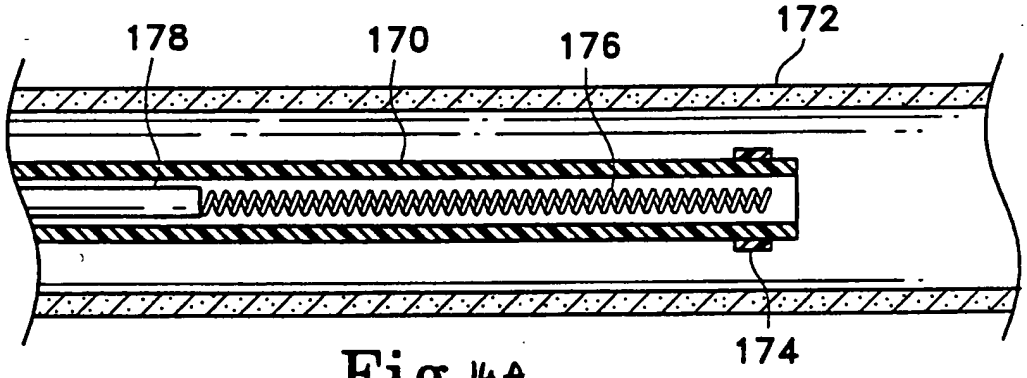



Fig. 14A

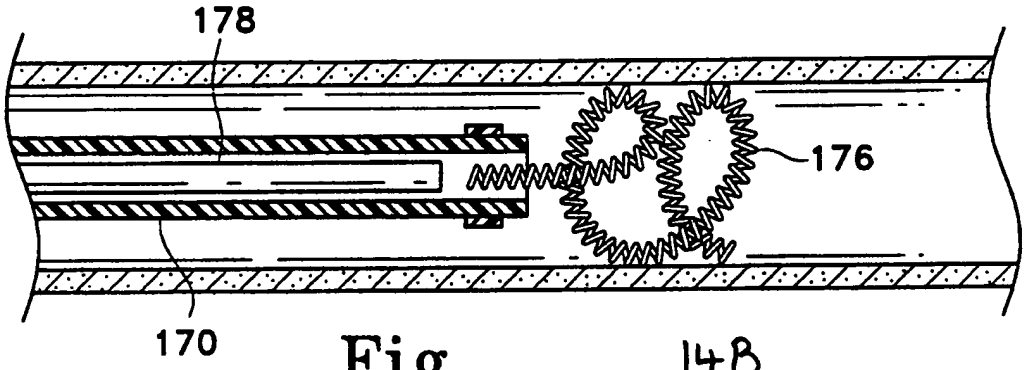



Fig. 14B

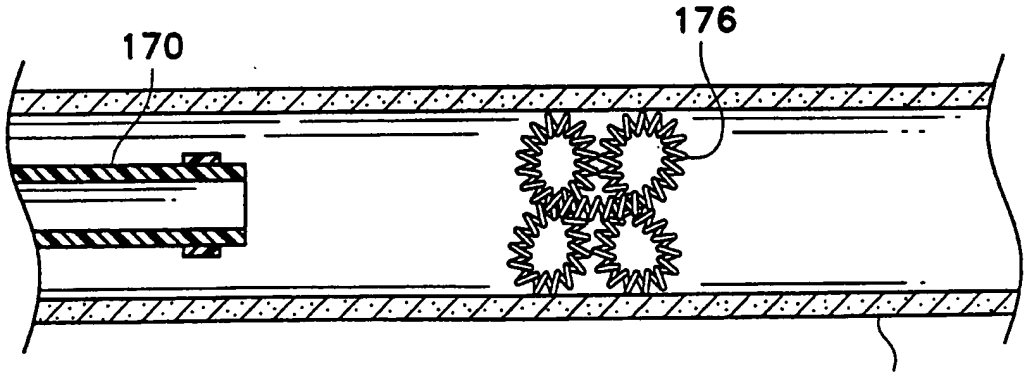



Fig. 14C